

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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THE PROCTER & GAMBLE COMPANY,

Plaintiff,

v.

ULTREO, INC.,

Defendant.
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:
: **Civil Action No. 07-8379 (RJS)**
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:
: **DECLARATION OF**
: **JAMES CHRISTOPHER McINNES**

I, **JAMES CHRISTOPHER McINNES**, hereby declare under penalty of perjury as follows:

Background And Qualifications

1. I am the Principal Scientist at Ultreo, Inc., and am responsible for all clinical and laboratory research. Prior to joining Ultreo in 2004, I was the Principal Scientist at Optiva Corporation and then subsequently at Philips Oral Healthcare, Inc., the makers of the Sonicare® power toothbrush.

2. I have over twenty years of experience in research and development ("R&D"), including coordinating and conducting clinical trials and laboratory studies in support of product claims and, along with several other colleagues, hold a number of patents relating to ultrasonic and other types or components of toothbrushes, as well as certain methods for quantitating the efficacy of oral care products.

3. I have written numerous journal articles, abstracts and invited articles on a variety of subjects in the field of oral health care, and have made presentations at a number of industry-related seminars and meetings.

4. I have a Bachelor of Science degree in mechanical engineering (BSME), and a

Ph.D. degree in bioengineering. I received both of these degrees from the University of Washington, Seattle.

5. I submit this Declaration in opposition to Procter & Gamble's ("P&G") request for a preliminary injunction and in response to the October 10, 2007 affidavit submitted by Dr. Aaron Biesbrock (the "Biesbrock Aff.") in connection with P&G's motion.

The Development Of The Ultreo® Power Toothbrush

6. The Ultreo® power toothbrush is the result of a long and exhaustive R&D effort led by Dr. Pierre D. Mourad of the University of Washington ("UW") and of UW's Center for Industrial and Medical Ultrasound, in conjunction with a number of my colleagues at Ultreo.

7. I was a member of the Ultreo team of engineers and scientists that took part in this project and have first-hand knowledge of Ultreo's efforts to develop the Ultreo® power toothbrush. In particular, I conducted a series of laboratory studies which sought to hone our knowledge of the various components of the Ultreo® and to help us to develop the product to the point where it was ready to be launched in the market.

8. The objective of these studies was to determine the optimal ultrasound, sonic and microbubble parameters that would contribute to the overall efficacy of our product. To this end, my studies focused on issues relating to: (a) bubbles in dental fluid; (b) the determination of the desired range of operating characteristics with respect to the Ultreo's® ultrasound parameters; and (c) the determination of the desired range of operating characteristics with respect to the Ultreo's® sonic parameters. I conducted these studies over the course of a three-year period (i.e., from 2004 through 2007), and investigated these issues in isolation and in combination. The research conducted over this three-year period, conducted both at Ultreo and at the University of Washington, helped us to ascertain the desired operating characteristics that

were ultimately employed within the Ultreo® power toothbrush. This research, along with the other studies conducted by Ultreo, convinced us that the Ultreo® was a safe and effective product that was ready to go to market. It is also important to note that the Ultreo® was designed to be used in a fluid environment such that the sonic movement of the bristles not only physically dislodges dental plaque from the teeth, but also generates bubbles within the dental slurry (toothpaste, water, and saliva) surrounding the teeth during normal brushing. Furthermore, the Ultreo® was designed so that the ultrasound would activate some of these bubbles and cause them to pulsate in response to the ultrasound pressure waves.

**The Proven Efficacy Of The Ultreo® Power
Toothbrush As Demonstrated In Clinical Studies**

9. The efficacy of the Ultreo® power toothbrush has been unquestionably established in a clinical context. In a series of three in vivo clinical studies, the Ultreo® power toothbrush has been demonstrated to be safe and effective in reducing and removing plaque from all surfaces, including hard-to-reach interproximal areas and in reducing gingivitis. These clinical studies, the details of which I will describe below, were conducted by Ultreo in conjunction with BioSci Research Canada Ltd. ("BioSci"), a leading independent clinical research facility that is used by P&G's Oral-B division, as well as other leading oral care companies.

10. In one clinical test, a total of 33 subjects participated in a study designed to evaluate the plaque removal efficacy of the Ultreo® power toothbrush after 1 and 2 minutes of brushing. The subjects were randomly assigned to one of two treatment arms: use of the Ultreo® for 1 minute, or use of the Ultreo® for 2 minutes. A product evaluation questionnaire was completed by the subjects at the conclusion of the study.

11. The Ultreo®/BioSci study concluded that:

- Use of the Ultreo® for both 1 minute and 2 minutes resulted in a significant reduction in plaque;
- The Ultreo® removed up to 95% of plaque from hard-to-reach interproximal areas during the first minute of brushing;
- The Ultreo® was effective in removing plaque from all surfaces, including interproximal, gumline, and posterior regions; and
- Subjects using the Ultreo® experienced an immediate feeling of clean teeth after brushing.

An abstract of this study is annexed hereto as Exhibit A.

12. In another clinical test involving 53 subjects, Ultreo and BioSci set out to evaluate the efficacy and the safety of the Ultreo® power toothbrush over a 30-day period in a population with mild to moderate gingivitis. The subjects were instructed to brush twice a day with their assigned toothbrush. Twenty-six subjects used the Ultreo® power toothbrush, and the remaining 27 subjects used the Oral-B® 35 manual toothbrush. A product evaluation questionnaire was filled out by the subjects at the end of the study.

13. The results of this study demonstrated that:

- The Ultreo® was shown to reduce gingivitis in 30 days;
- The Ultreo® was significantly more effective in reducing gingivitis than a manual toothbrush;
- Subjects using the Ultreo® perceived clean teeth and improved gingival health; and
- Both toothbrushes were found to be safe, as no adverse events were reported.

An abstract of this study is annexed hereto as Exhibit B.

14. Although this study focused on gingival health, data were also recorded with respect to the removal of dental plaque at both clinical visits. Overall plaque removal was 75% for the Ultreo® and 66% for the manual toothbrush at the first visit, and 71% for the Ultreo® and 67% for the manual toothbrush at the second visit. Although the Ultreo® removed numerically more plaque at both visits, the differences were only statistically significant at the first visit.

15. In yet another clinical study conducted with BioSci involving 22 subjects, the Ultreo® power toothbrush was shown to be safe and effective in reducing extrinsic stains on teeth. An abstract of this study is annexed hereto as Exhibit C.

**The Proven Efficacy Of The Ultreo® Power
Toothbrush As Demonstrated In Laboratory Studies**

16. Laboratory studies are well-established and respected methodological tools used by members of the dental health research community in assessing both the safety and the effectiveness of oral hygiene products. I respectfully refer the Court to the Declaration of Dr. Joel Berg for an explanation of why this is the case. As described below, laboratory studies have unequivocally proven the efficacy of the Ultreo® power toothbrush

The University Of Washington Study Of The Ultreo® Power Toothbrush

17. Ultreo, in conjunction with the University of Washington, has conducted laboratory research that has demonstrated that the Ultreo® power toothbrush's combined use of ultrasound waveguide technology and sonic bristle action can remove more plaque bacteria than either element used in isolation, and can remove plaque bacteria absent physical contact by the bristles. This research at the University of Washington led to a specific laboratory study in which the Ultreo® was compared to other power toothbrushes (the "UW Study"). An abstract of the UW Study is annexed hereto as Exhibit F.

18. The UW Study was designed based on published research by other power toothbrush manufacturers, notably Philips, in which a power toothbrush was studied for its ability to remove plaque bacteria in vitro without bristle contact. Ultreo sponsored the UW Study under the direction of Dr. Frank Roberts of the UW School of Dentistry, Department of Periodontics. I assisted in the design and execution of this research using my knowledge gained in studying the Sonicare's ability to remove dental plaque bacteria in vitro without bristle contact. Dr. Roberts' laboratory personnel, Beth Hacker, Ph.D., an experienced research scientist, and Teresa Oswald, a microbiologist, handled the day-to-day activities associated with this research. Dr. Hacker and Ms. Oswald have no financial interest in or ownership ties to Ultreo.

19. In the UW Study, a biofilm of *Streptococcus mutans* ("*S. mutans*"), a particularly adhesive plaque bacteria, was grown on "hydroxyapatite" discs. Hydroxyapatite, also referred to as "hydroxylapatite," is a type of mineral, forms of which are found in dental enamel (the visible dental tissue of a tooth) and in dentin (the calcified tissue that lies beneath the dental enamel). The bacteria-coated discs were positioned three millimeters away from the bristle tips or ultrasound waveguide of: (a) an Ultreo® power toothbrush with the ultrasound device activated; (b) an Ultreo® power toothbrush with the ultrasound deactivated; (c) a Sonicare Elite® sonic power toothbrush; and (d) P&G's Oral-B Triumph® oscillating brush power toothbrush. The UW Study results showed that the ultrasound-activated Ultreo® power toothbrush removed significantly more plaque bacteria without bristle contact than the other three power toothbrush treatments.

20. In the same study, an *S. mutans* biofilm was grown on grooved glass slides. The surfaces of the slides were then brushed with the bristle tips of all four toothbrushes. Notably, the UW Study results showed that plaque bacteria within the grooves was observed to be

substantially removed by the Ultreo® and removed to a lesser extent by other power toothbrushes.

21. In sum, these test procedures plainly show that the Ultreo® toothbrush's ultrasound technology can remove plaque bacteria that toothbrush bristles cannot reach.

22. Claiming that a power toothbrush can remove plaque beyond the reach of its bristles is not unique to Ultreo. Philips, the current maker of Sonicare®, also claims in its advertising that its Sonicare® power toothbrush cleans beyond the reach of its bristles.

23. Significantly, Sonicare® substantiates its beyond-the-bristles cleaning claim with laboratory – not clinical – studies. The in vitro study relied upon by Philips is annexed hereto as Exhibit G.¹ Thus, P&G's global assertion that the standard industry practice is that all toothbrush efficacy claims be substantiated with clinical research is untrue. Philips is the market leader with respect to premium power toothbrushes and is making beyond-the-bristles plaque removal claims while relying *solely* upon laboratory studies. Indeed, the UW Study is substantially similar to many of the Sonicare studies and borrows upon published laboratory methods.

24. Indeed, P&G itself has made beyond-the-bristles cleaning claims – based on the results of laboratory studies. Annexed hereto as Exhibit H (PG007055-104) is a copy of an October 2004 compendium of studies produced by P&G in this action which is entitled "A Supplement To Compendium Of Continuing Education In Dentistry: Review Of Clinical Research On The IntelliClean System® From Sonicare® And Crest®." The first page of the Compendium prominently states that it is "[s]upported by Philips Oral Healthcare, Inc. and The Procter & Gamble Company." (PG007055).

¹ Aspiras, M, Elliott, N, Nelson, R, et al. In vitro evaluation of interproximal biofilm removal with power toothbrushes. *Review of Key Clinical Research on the New Philips Sonicare FlexCare: A Supplement to Compendium of Continuing Education in Dentistry* 2007;28: 10-14 (Exhibit G hereto).

25. The IntelliClean System® was an integrated Sonicare® power toothbrush and Crest® liquid-toothpaste dispensing system that P&G had developed in conjunction with Philips. That product was jointly marketed and sold by P&G and Philips, but is no longer being offered by these two companies. One of the laboratory studies involving the IntelliClean System® which is contained in the Compendium is a study on which I am listed as a co-investigator. That study is entitled "In Vitro Evaluation Of The Efficacy And Safety Of The IntelliClean System: Interproximal Biofilm Removal And Dentin Substrate Wear." (Exhibit H at PG007098-104). Notably, the statements made in that joint Philips/P&G study squarely contradict the claims that P&G is making in this litigation. The study confirms that "in vitro test methods . . . provide objective analyses of the efficacy and safety of these oral hygiene products," and that they "provide methods of assessment of product efficacy representative of *what would be found in the oral cavity*," i.e., the mouth. (PG007104) (emphases added).

26. Indeed, that study also found that the amount of plaque biofilm removed from hydroxyapatite disks by the IntelliClean System® absent physical bristle contact was significantly greater than that removed by an Oral-B® brand rotating/oscillating toothbrush. The Oral-B® brand toothbrush is, of course, the type of power toothbrush that P&G, as a result of acquiring Gillette and its Oral-B® brand in 2005, currently manufactures. The study concluded that:

The IntelliClean System® toothbrush, with its associated dynamic fluid activity, demonstrates superior removal of biofilm as compared to a power toothbrush with conventional rotating/oscillating bristle motion [and that] [t]he results presented here validate that the IntelliClean System® is both safe and efficacious and provide the consumer and dental professional with information allowing an informed choice in oral hygiene product selection.

(Exhibit H at PG007104).

27. Other articles in the Compendium confirm that P&G has extolled the virtues of beyond-the-bristles cleaning claims based on laboratory studies. For instance, the lead article in the Compendium, which is co-authored by a P&G Senior Scientist and which is entitled "A Novel Oral Hygiene System Through Integration Of A Sonic Toothbrush And Liquid Toothpaste" (Exhibit H at PG007058-61), explains that central to the Sonicare® toothbrush within the IntelliClean System® is its "side-to-side motion of the bristle tips[], which creates dynamic fluid activity in the mouth," and that "[a]ccording to in vitro studies conducted by Hope and Wilson[] and Adams and colleagues[], such fluid activity can remove plaque from beyond the reach of the bristles significantly better than a rotational-oscillation power toothbrush." (PG007059). That same article states that, like other Sonicare® toothbrushes, the IntelliClean System® "has also been shown in vitro by Yuen and coworkers[] to exhibit 'beyond-the-bristles' cleaning and to be gentle on dentin, significantly more so than the Oral-B® ProfessionalCare7000, a leading rotational oscillation toothbrush." (PG007061).² Significantly, nowhere in that article do the authors state that the results of laboratory or in vitro studies upon which they have relied must be corroborated by clinical studies.

28. Similarly, in an article regarding a clinical gingivitis study co-authored, in part, by a P&G Senior Scientist and a P&G Senior Statistician, and entitled "Effect Of A Novel Integrated Power Toothbrush And Toothpaste Oral Hygiene System On Gingivitis" (Exhibit H at

² Collectively citing Hope, CK, Wilson, M. Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using in vitro oral biofilms. *Am. J. Dent.* 2002; 15 (spec no): 7B-11B (Exhibit L hereto); Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. [Published correction appears in *Am. J. Dent.* 2002;15-46]. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (Exhibit I hereto); Yuen, AF, Nelson, R, Johnson, MR, et al. In vitro evaluation of the efficacy and safety of the IntelliClean System: interproximal biofilm removal and dentin substrate wear. *Compend. Contin. Educ. Dent.* 2004;25 (suppl. 1):44-50 (Exhibit J hereto).

PG007069-74), the authors note that: "[u]nlike many power toothbrushes, the Sonicare® toothbrush was designed to deliver not only physical bristle contact with the teeth to remove plaque[,] but also a fluid dynamic action derived from the bristle motion that has been shown in vitro to disrupt plaque biofilms." (PG007070).³ And, in another article regarding a clinical study, entitled "Plaque Reduction Over Time Of An Integrated Oral Hygiene System" (Exhibit H at PG007062-68), the co-authors echo this sentiment about in vitro studies, stating that "[i]n certain power toothbrushes, notably the Sonicare® toothbrush, the brush's high frequency motion not only cleans by direct bristle-tooth contact[,] but also creates dynamic fluid pressure and shear forces that have been shown in laboratory studies to disrupt and disperse bacterial plaque beyond the reach of the bristles." (PG002137).⁴

29. Moreover, another article written by P&G scientists in the Compendium is entitled "Pharmacodynamic And Pharmacokinetic Effects In Gingival Crevicular Fluid From Re-dosing During Brushing" (Exhibit H at PG007075-81). I note that one of the authors, Dr. Tao He of P&G, is also a co-author of the P&G Clinical Study, discussed below, which P&G has offered in connection with this action in order to evaluate the effectiveness of the Ultreo®. In the Compendium article, Dr. He and his co-authors refer to the "proven hydrodynamic action of sonic brush technology" (PG007076) and cite to support that statement an in vitro study that

³ Citing Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (Exhibit I hereto); Hope, CK, Petrie, A, Wilson, M. In vitro assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (Exhibit K hereto).

⁴ Citing Hope, CK, Wilson, M. Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using in vitro oral biofilms. *Am. J. Dent.* 2002; 15 (spec no): 7B-11B (Exhibit L hereto); Hope, CK, Petrie, A, Wilson, M. In vitro assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (Exhibit K hereto); Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (Exhibit I hereto).

examined the plaque-removing ability of hydrodynamic shear forces to clean beyond-the-bristles. (PG007081).⁵ The word "proven" is not one that is used lightly by scientists and at no point in the article do Dr. He and his co-authors state that such proof can only be obtained through clinical studies.

30. P&G has, in short, made beyond-the-bristles claims for its own integrated oral care products. As noted above, those claims have been made on the basis of laboratory studies which, by P&G's own admission, demonstrate the safety of such products and the efficacy of their beyond-the-bristles cleaning capabilities.

Other Laboratory Studies Have Proven The Safety Of The Ultreo®

31. A laboratory study conducted at the Pacific Dental Institute in Portland, Oregon set out to compare the Ultreo® toothbrush to two controls (a manual toothbrush and a power toothbrush) after a simulated 1-year brushing period with respect to wear on natural tooth surfaces, cements and restorative materials. The results of this study have shown that the Ultreo® power toothbrush is gentle on natural tooth surfaces and restorative materials. Similarly, a laboratory study conducted at the same Institute set out to compare the Ultreo® toothbrush to two controls (a manual toothbrush and a power toothbrush) after a simulated 2 year brushing period with respect to retention force of orthodontic brackets and crowns. This study found that none of the treatments significantly affected the retention force of orthodontic brackets and crowns. Abstracts of these studies are annexed hereto as Exhibits P and Q.

32. Moreover, a separate in vitro study conducted at the University of Washington set out to evaluate the safety of the Ultreo® power toothbrush's sonic and ultrasound processes using

⁵ Citing Hope, CK, Petrie, A, Wilson, M. In vitro assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (Exhibit K hereto).

in vitro models of soft tissue. The study found that the Ultreo® power toothbrush does not harm soft tissue cells. An abstract of this study is annexed hereto as Exhibit R.

The Affidavit Of Dr. Aaron Biesbrock

33. I have read the affidavit that Dr. Biesbrock has submitted in support of P&G's request for a preliminary injunction. His criticisms of in vitro studies and of Ultreo's UW Study are wholly without merit for a number of reasons.

34. I have reviewed certain documents produced to Ultreo by P&G (Exhibit S at PG000672-81) that unequivocally show that P&G's own laboratory studies, which have replicated the methodologies that were used in Ultreo's UW Study, demonstrate that the ultrasound-activated Ultreo® removed significant quantities of plaque bacteria without bristle contact.

35. In a series of laboratory studies, P&G compared the Ultreo® with and without its ultrasound activated, to the Sonicare Elite® power toothbrush and the Oral-B® power toothbrush, using hydroxyapatite discs and plaque biofilm.

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36. Dr. Biesbrock's criticisms of in vitro studies in general are also misguided. His contention that the type of bacteria that is used in in vitro studies "does not mimic the complex plaque bacteria that is found in the human mouth (and on teeth)" is wrong. (Biesbrock Aff. at ¶ 14). He notes, in a rather hyperbolic fashion, that "30 to 300" types of plaque bacteria exist. (Biesbrock Aff. at ¶ 14).

37. One of those strains or types of bacteria, however, is *S. mutans* – the bacteria used in the above-mentioned UW Study of the Ultreo® power toothbrush. It is well-established that

S. mutans is commonly found in the human mouth. It is especially suited for use in dental research studies precisely because the tenacious nature of its growth in the laboratory is a model for the properties of naturally-forming plaque bacteria in the human mouth.

38. Moreover, it is also widely-recognized within the dental profession that *S. mutans* is a particularly harmful strain of bacteria. This type of bacteria is a leading cause in the formation of dental "caries," a type of disease that affects the structure of human teeth. When left untreated, dental caries lead to the formation of what the lay public commonly recognizes as "tooth decay" and "cavities."

39. Dr. Biesbrock's claim that "[t]he presence of salivary protein in the mouth may also impact the effectiveness of plaque-removal efforts" (Biesbrock Aff. at ¶ 16), and that this fact compromises the validity of in vitro study results, is similarly misplaced. As noted above, in the UW Study, a biofilm of *S. mutans* was grown on hydroxyapatite discs. The surface of the hydroxyapatite discs was coated with gastric mucin. Gastric mucin is a well-recognized substitute for naturally-occurring human saliva in laboratory studies and is routinely used by dental researchers. Indeed, Philips also uses gastric mucin in its in vitro studies.⁶ Accordingly, the methodology employed in the UW Study takes into account the impact that the presence of salivary proteins may have on plaque removal efforts.

40. Dr. Biesbrock's all-encompassing statement that in vitro studies are not accurate predictors of in vivo plaque removal efforts because "most of these in vitro studies are conducted with the toothbrush head fully submerged in water (or a similar liquid)," and because "an

⁶ See Hope, CK, Wilson, M. Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using in vitro oral biofilms. *Am. J. Dent.* 2002; 15 (spec no): 7B-11B (Exhibit L hereto); Hope, CK, Petrie, A, Wilson, M. In vitro assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (Exhibit K hereto).

individual's mouth is never completely filled with saliva" (Biesbrock Aff. at ¶ 17), is also incorrect.

41. During the course of the UW Study, the Ultreo® power toothbrush head was *not* fully submerged in water or any other fluid. Indeed, just a portion of the Ultreo's® toothbrush head's bristles were immersed in fluid. This partial-submersion protocol was used because the presence of air is integral to the formation of bubbles, which is an important factor with respect to the plaque removal capabilities of the Ultreo® toothbrush. Not surprisingly, Philips also uses a partial-submersion protocol in its "beyond-the-bristles" *S. mutans* laboratory studies.⁷

42. Furthermore, Dr. Biesbrock's intimation that in vitro studies using a full-submersion testing protocol are deficient because the volume of saliva found in the human mouth at any given time is "1.07 milliliters, plus or minus 0.39 milliliters" (Biesbrock Aff. at ¶ 17) is quite misleading and, as explained below, simply inapplicable to the actual protocol employed in the UW Study of the Ultreo® toothbrush.

43. Dr. Biesbrock fails to note that 1.07 milliliters of saliva may be found in the human mouth when the mouth is in a *passive* or *resting* state. By way of example, one's mouth is in a passive or resting state when one is not eating. Studies show that when stimulated, for example, by chewing or brushing, saliva is generated at a rate greater than 2 milliliters per minute.⁸ Thus, during a typical two-minute brushing, an additional 4 milliliters of fluid (saliva) may be generated in addition to resting saliva. Moreover, additional fluid is introduced into the

⁷ See Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. [Published correction appears in *Am. J. Dent.* 2002;15-46]. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (Exhibit I hereto); Wu-Yuan, C, McInnes, C. Ability of the Sonicare® electronic toothbrush to generate dynamic fluid activity that removes bacteria. *J. Clin. Dent.* 1994;5 89-93 (Exhibit N hereto).

⁸ See Bergdahl, M. Salivary flow and oral complaints in adult dental patients. *Community Dent Oral Epidemiol* 2000;28: 59-66 (Exhibit O hereto).

mouth in the form of water that one puts on a toothbrush before beginning to brush. Since saliva is being generated during brushing, the amount of fluid in the mouth varies during a brushing episode, but all told, there are approximately 2 to 6 milliliters of fluid in the mouth, rather than the 1.07 milliliters cited by Dr. Biesbrock. Indeed, in an in vivo test conducted early in Ultreo's® development, I set out to measure the amount of fluid customarily found in the human mouth during typical brushing with a power toothbrush. Based on expectorated fluid from 7 volunteers, I found that the amount of fluid in the mouth after 60 seconds of brushing ranged from approximately 1.5 to 6.8 milliliters, for an average of 4.5 milliliters.

44. Furthermore, Dr. Biesbrock's statement that "in some in vitro studies, the surface that is intended to represent teeth is often not an acceptable substitute" (Biesbrock Aff. at ¶ 17), is inapplicable to the UW Study of the Ultreo® toothbrush. As noted above, hydroxyapatite discs contain the mineral found in dental enamel and in dentin and are commonly used within the scientific community as an appropriate substitute for teeth. Indeed, Philips has been using them for years in their clinical studies involving the Sonicare® power toothbrush. Moreover, P&G's own documents confirm the appropriateness of using hydroxyapatite discs.

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45. Moreover, in the UW Study, a biofilm of *S. mutans* was also grown on grooved glass slides, the surfaces of which were brushed with bristle tips of all four toothbrushes. The results showed that plaque bacteria within the grooves was observed to be substantially removed by the Ultreo® and removed to a lesser extent by other power toothbrushes. Significantly, Philips has also used glass slides, in addition to hydroxyapatite disks, in laboratory testing of its

Sonicare® line of power toothbrushes.⁹

46. Finally, Dr. Biesbrock's contention that "some in vitro studies fail to use toothpaste, which can have an impact on both bacteria and plaque" (Biesbrock Aff. at ¶ 17), also has no application to the UW Study. The UW Study of the Ultreo® power toothbrush *did* use toothpaste.

P&G's Clinical Study Is Deficient In Several Major Respects

47. I have reviewed P&G's clinical study, entitled "A Clinical Study Evaluating the Effects of a Sonic Toothbrush with Ultrasound Waveguide in Disrupting Plaque with and without Bristle Contact" (the "P&G Clinical Study"). That study, which appears to have been conducted internally at P&G, is authored by four P&G employees. I believe the test is seriously flawed in a number of respects and, it appears, was specifically designed to achieve the results that P&G desired.

48. The P&G Clinical Study fails to demonstrate anything about the contribution of *ultrasound* to the Ultreo® power toothbrush's plaque removal capabilities. The study did not, as one might expect, compare the Ultreo® toothbrush with its *ultrasound* component *activated*, to the Ultreo® with its ultrasound component *deactivated*. Instead, the study compared the Ultreo® toothbrush turned on (thus activating both the sonic and ultrasound processes), with the Ultreo® toothbrush turned off (thus deactivating both the sonic and ultrasound processes). The contribution of ultrasound was not isolated.

49. The study also purports to mirror the UW Study by directing that the Ultreo® power toothbrush brushhead be held by a dental hygienist at a three millimeter distance from the

⁹ Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. [Published correction appears in *Am. J. Dent.* 2002;15-46]. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (Exhibit I hereto).

tooth surface of the subject.

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50. Another fundamental problem with this approach in an in vivo context is that with the mouth open for the hygienist to perform the brushing, there will not be sufficient fluid near the ultrasound waveguide tip of the toothbrush to allow the ultrasound to work. It is impossible for a patient to keep his or her mouth open so as to permit a hygienist to observe the activity and still maintain a realistic fluid environment typical of normal brushing. This means that the ultrasound will not be able to activate microbubbles so that they can pulsate and help clean teeth.

51. Documents produced by P&G also suggest that P&G employees were used as subjects in this study.

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In a study involving a competitor's toothbrush, where subject behavior can influence the outcome, the use of employees cannot, under any stretch of the imagination, be considered unbiased.

52. The P&G Clinical Study also purports to show that the Ultreo® power toothbrush performs better when used as a manual toothbrush, rather than as a power toothbrush. This result is inconsistent with Ultreo's own clinical research, which shows that the Ultreo® power toothbrush outperforms a manual brush in both overall and interproximal plaque reduction. The

result is also inconsistent with Oral-B's own clinical research, which indicates that its power toothbrushes consistently outperform manual toothbrushes. Philips' research similarly shows that its power toothbrush will outperform a manual toothbrush. In light of all this research, it has become accepted in the dental research community that a power toothbrush is superior to a manual toothbrush.¹⁰

53. In sum, I believe that there are a number of major deficiencies in P&G's clinical study and that its purported results should be dismissed.

P&G's Reliance On The Philips In Vivo Study Of The Ultreo® Is Misplaced

54. Dr. Biesbrock claims that Philips' in vivo study that purports to measure the plaque removal capabilities of the Sonicare FlexCare® and the Ultreo® (with its ultrasound function activated and disabled) is relevant is assessing the overall efficacy of the Ultreo®. (Biesbrock Aff. at ¶ 36 and Exhibit S). I disagree. The only information upon which Dr. Biesbrock bases his claim about the Philips study is an abstract published by Philips. P&G is simply not in any position to opine on the validity of Philips' purported results since the parties do not have the underlying data that supports this study.

55. Also, it is instructive to note that in the course of this study, Philips "disabled" the ultrasound function of the Ultreo® power toothbrush. In other words, it appears that Philips dismantled the Ultreo® power toothbrush. Given the lack of information that Ultreo has about the Philips' study, we are unable to assess whether Philips' actions in taking the Ultreo® apart have had an adverse impact upon the capabilities of the Ultreo®, or have in some manner artificially enhanced the power of the Ultreo's® sonic bristle motion when the ultrasound was

¹⁰ I am not currently aware of any P&G documents that shed light on the type of instructions P&G issued to subjects with respect to the use of the Ultreo® as a manual toothbrush. The lack of any written instructions would, of course, raise yet another serious issue about the methodology employed by P&G during the course of this study.

disabled.

56. Finally, and for the reasons explained by Dr. Berg in his declaration, it is generally recognized that traditional, visible examination techniques utilized by researchers during the course of clinical research studies are fraught with a number of limitations. These indices are highly subjective and are not sensitive enough to record all differences in plaque removal.

57. For example, the Turesky Plaque Index (a grading of plaque with scores from 0 to 5) used by P&G in its study, assigns a score of 5 to any plaque that covers more than two-thirds of the tooth surface. A tooth that is fully covered with plaque before brushing (a Turesky score of 5) and only two-thirds covered with plaque after brushing (a Turesky score of 5) is therefore scored by this subjective index as having no plaque removal (5 before minus 5 afterwards results in 0 removal). Thus a full one-third of plaque may be removed from the tooth surface but be scored as having no plaque removal. Furthermore, since the Turesky index considers only the area covered with plaque, and not thickness, the plaque may be substantially thinned but not totally removed and thus also not receive a change in plaque score via this index.

58. Also, since plaque index scores rely on examination of the tooth surface by normal visual acuity, removal of plaque from regions smaller than those that can be seen by the human eye is not detected. Individual plaque bacteria are on the order of 1 micrometer – too small to be seen without magnification. Hundreds of thousands of bacteria may fit on a rounded dot made by a pencil.¹¹ Scaled accordingly, hundreds of millions of bacteria may be covering an individual tooth that has been scored a 5 on the Turesky scale. The fact that one-third of the plaque bacteria can be removed with no change in plaque score means that hundreds of millions

¹¹ See *Bacteria*. MSN Encarta: http://encarta.msn.com/text_761574409_0/Bacteria.html (November 27, 2007) (Exhibit M hereto).

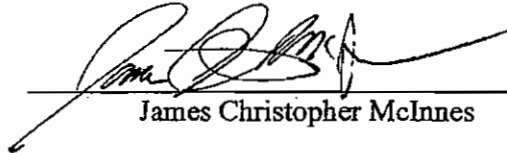
of bacteria can be removed, but not detected via these visual indices. These visual plaque indices have utility in assessing the overall general oral health status of subjects, but were never designed with enough sensitivity to assess fine differences in plaque removal.

59. Furthermore, since mechanical brushing by subjects removes so much of the visible plaque on teeth, it is difficult to evaluate through visual examination whether there are any additional benefits achieved from other technological components of power toothbrushes, such as those contained in the Ultreo® power toothbrush.

The Ultreo® Toothbrush Generates Approximately 4 Million Cycles of Ultrasound Energy

60. I have calculated the number of cycles of ultrasound energy generated by the Ultreo® power toothbrush. Attached as Exhibit E hereto are the documented results of my calculation. The Ultreo® power toothbrush generates approximately four million cycles of ultrasound energy per two-minute brushing.

Dated: November 29, 2007
Redmond, Washington



James Christopher McInnes

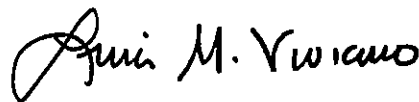
CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on November 30, 2007, I caused a copy of the foregoing **REDACTED DECLARATION OF JAMES CHRISTOPHER McINNES** to be served upon counsel for The Procter & Gamble Company by the Court's ECF Filing System and by hand delivery to the following individual:

Laura W. Sawyer
JONES DAY
222 East 41st Street
New York, New York 10017

Attorneys for The Procter & Gamble Company

Dated: New York, New York
November 30, 2007

A handwritten signature in black ink, reading "Lina M. Viviano", written in a cursive style.

Lina M. Viviano